

Attorney's Docket No.: 10790-072001 / CGL02/124US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Michael A. Porter Art Unit : 1761
Serial No. : 10/722,359 Examiner : Anthony J. Weier
Filed : November 25, 2003 Conf. No. : 4715
Title : MODIFIED OILSEED MATERIAL WITH A HIGH GEL STRENGTH

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DECLARATION OF JEROME L. SHEN UNDER 37 C.F.R. §1.132

I, Jerome L. Shen, hereby declare:

1. I have 28 years experience as research scientist in the field of soy protein manufacturing and functional modification. I especially have expertise in the area of membrane filtration as having worked to developed processes in membrane processing especially with regard to hydrolyzed soy proteins. I have worked at the lab, pilot plant, and plant level in developing theses processes. I have dealt with the costs and feasibility of the commercialization of these processes. I have also worked extensively to improve the color, flavor, and functional characteristics of soy protein products as well as in the characterization of these products. I am the author of a number of patents in this area.
2. I have read and reviewed Lawhon, U.S. Patent No. 4,420,425 ("the '425 patent").
3. It is my opinion that a person of ordinary skill in the art cannot accurately reproduce the method as described in the '425 patent for the following reasons:
 - a. The '425 patent states that the ultrafiltration process will work with all types of membranes, but also declares that certain operating conditions (e.g., prefiltration

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- and viscosity conditions) are dependent on the membrane. Despite these statements, the '425 patent fails to provide any examples of specific membranes;
- b. The '425 patent provides data on flux rates, but does not provide the pressures necessary to maintain those rates;
 - c. The '425 patent states that keeping the solids level low will maintain a good flux rate, but the patent provides neither data nor sufficient discussion to indicate the acceptable operating range for solids;
 - d. The '425 patent does not give information on how long specified flux rates can be maintained, nor how often the membranes need to be cleaned to maintain those rates. This is a critical factor, as the time between cleanings spells the difference between a commercially viable process and an academic exercise; and
 - e. The data provided in the '425 patent does not make sense in every case. For example, the material balance data in Table 5 shows that 48% of the extracted ash and 27.5% of the extracted sugars are retained by the ultrafiltration membranes. If that is correct, the product would not be an isolate (90% protein), because a typical extract (feed) is approximately 64% protein dry basis and from the retention data in table 5, the resulting product will have approximately 75% protein dry basis. This data also indicates a very ineffective ultrafiltration. Certainly, many of the flavor and color compounds present in the material will be retained by the ultrafiltration process along with the small sugar and ash molecules.
4. An important reason why a person skilled in the art cannot reproduce this method is due to the inconsistency of the method itself. Thus, the characteristics and properties of the output cannot be predicted with any level of confidence. For example, the '425 patent states that example 3 was a repeat of example 1, conducted under approximately the same conditions. Unfortunately, the '425 patent does not give analytical data for the product from example 3, so product 3 data cannot be fully compared with product 1 data. However, the '425 patent does provide membrane retention data for both examples 1 and 3 in Table 5. Table 5 shows that there were large differences in the retention of ash (57.2% vs. 37.1%), in the retention of sugars (29.4% vs. 24.6%), and in the retention of

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non-protein nitrogen (51.5% vs. 30.1%). All these compounds are small molecular mass compounds that should be effectively removed into the permeate if the membrane was operating properly and the ultrafiltration was effectively carried to completion. Yet the process, under similar conditions as practiced by the inventors, produced significantly different results in two trials. These results also bring into question statements in the patent that the process removes flavor and color compounds (which are small molecules). If other small molecules, such as ash, sugars, and non-protein nitrogen compounds, are not effectively removed, it is likely the off-flavor compounds are also not effectively removed. Thus, it is very likely that the product of examples 1 and 3 will also have different flavor and color characteristics.

5. There are unspecified variables that can affect the properties of the final product, even if one reproduces the process of the '425 patent as far as able. The major unspecified variables include the ultrafiltration conditions and their effect on removal of ash, sugars, flavor, odor, and color compounds. The unspecified operating conditions can have a great effect on what is removed in ultrafiltration, and on the resulting product:
 - a. This is demonstrated by the poor reproducibility illustrated by examples 1 and 3 (shown in Table 5), as example 3 retained much less soluble sugars, non-protein nitrogen, and ash than example 1. This strongly indicates that even under the same method as conducted by Lawhon, the process will produce variable products;
 - b. The retention of small molecules such as sugars, non-protein nitrogen, and ash indicates that flavor, odor, and color compounds (also small soluble molecules), are also retained. The retention of these types of compounds will cause off flavors and colors in the resulting product. Thus, the '425 patent method does not, in my opinion, demonstrate a product with better flavor and color, as stated. Although there is color data given, the data shows that the color is no better or slightly inferior to commercial isolates. The color data alone is not enough to distinguish the claimed product from soy protein products produced by other processes. Furthermore, there is no flavor data given at all. Thus, there is no way to determine the quality of the product made by the patent methods; and

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- c. One crucial premise of the patent is the removal of small molecular mass flavor and color compounds. However, whether these compounds are actually removed or not depends on the efficient operation of the ultrafiltration process. The operating parameters of the ultrafiltration process greatly affect what is and what is not retained. In order to define a product of this process, additional information, such as the operating parameters, the process mass balance, or the final analysis of the product corresponding to the defined process should be provided. In the '425 patent, the process definition is incomplete and the complete characteristics of the product are not given. Thus, even if a person skilled in the field reproduces a similar process, this person would not know if he has reproduced the claimed product. What is given in the '425 patent in my opinion is not enough to define a product for those skilled in art. The product characteristics that are provided can cover many different isolated soy products.
6. For all of these reasons, one of skill in the art cannot accurately reproduce the method of the '425 patent with any degree of confidence, and cannot accurately predict the characteristics of a product produced using the method of the '425 patent.
7. I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Dated: 12/12/2006

Jerome L. Shen
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